SEP 1 6 2003

K030719

510(K) SUMMARY

substantially equivalent

General Information

Applicant's Name and Address:	OCULUS Optikgeräte GmbH Münchholzhäuser Straße 29 D-35582 Wetzlar
Date of Summary:	04 March 2003
Owner/Operator Number:	8010318
	Mr. Joerg Iwanczuk Product Manager

Device Name

Trade Name:	Pentacam Scheimpflug Camera
Class:	Class II
Classification Name:	Scheimpflug Camera
Product Code:	MXK Anterior Eye-Segment Analysis System
Regulation Number:	886.1850

Predicate Devices

The Pentacam Scheimpflug Camera is claimed to be substantially equivalent to the following currently market device:

NIDEK, EAS-1000 Anterior Eye-Segment Analysis System- K991284

Device Description:

The Pentacam Scheimpflug Camera is a non-invasive, diagnostic system created to take photographs of the anterior segment of the eye, table mounted and AC powered. The system is based on the Scheimpflug Principle for Slit Image photography. The device consists of a measurement unit, power supply and a CPU. The measuring system uses blue light (UV-free) given to a slit to illuminate the eye, and a CCD-Camera for photography. The measuring system offers the possibility of automatically rotation to get photographs of every part of the eye. The system calculates from the photos a 3D-modell of the eye.

Product Comparison

	New Device	Anterior Eye-Segment Analysis System
Manufacturer	OCULUS Optikgeräte GmbH	Nidek Inc.
Measuring Principle	Scheimpflug Principle for Slit Image photography	Scheimpflug Principle for Slit Image photography
Optical	Single Aperture	Single Aperture
Viewing Optics	15" Coloured Screen	5.5" Black and White CRT
Observation Illumination	Infrared LED 800nm	Infrared LED for Retro-Illumination 800nm
Flash Output Illumination	Blue LED Light (UV-free) 475nm, max. 2.5Wsec	Xenon Lamp 200Wsec
Photography Camera	CCD-Camera	CCD-Camera
Display	Data digital, displayed on a CPU	Data digital and can be displayed on a CPU
Image resolution	800 x 600 pixels	640 x 400 pixels
Image size	5.6 x 4.5mm	8mm x 6.6mm
Photographic range	Eligible 0 to 180°	Offers Photographic angles from 0 to 180°
Photographic Series	1 to 50 photos	N/A
Slit Length	14mm	2 – 14mm adjustable
Power Consumption	50VA	150 VA
Power requirement	110/220 VAC, 50/60Hz	100VAC, 50/60Hz
Weight	9 kg	25 kg

Basics for Substantial Equivalence

- The systems utilize the same or similar Operating System. They contain:
  - An optical system
  - A source of illumination for observation and photography
  - A CCD-Camera as photographic medium
- Both systems have the same intended use to measure the eye and the anterior eye segment
- Both systems use the same device features like a
  - Head stabilizing device
  - External fixation target
  - Joy stick for control mechanism
- Both systems are considered "Non Invasive" as defined in 21 CFR §812.3(k) and considered not to be a "Significant Risk Device" as defined in 21 CFR §812.3(m)

Indications for Use

Intended Use: The Pentacam is designed to take photos of the anterior segment of the eye, which includes cornea, lens and anterior chamber. To evaluate:

Corneal shape

Analyse condition of the lens

Densitometry, cataract degree and location using the Scheimpflug Image

State of the lens (pre and post intraocular lens implant)

Analyse anterior chamber (size, volume and angle)

Pachymetry (thickness of the cornea)

Scheimpflug Image

Analysing center position of the cornea to iris and lens

Safety

The Pentacam is a non-invasive diagnostic system, which contacts the patient only on his/her chin and forehead. The Pentacam does not present or pose any new or additional effects for risk on the safety prescribed intended uses. The light output is of an eye safe intensity and wavelength. The electrical safety requirements for medical devices are met. The Pentacam is proven effective for its intended uses through internal company and independent clinical studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2003

OCULUS Optikgeräte GmbH
c/o Tom Weatherby
18902 NE 150th St.
Woodinville, WA 98072

Re: K030719
Trade/Device Name: Pentacam Scheimpflug Camera
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slitlamp biomicroscope
Regulatory Class: Class II
Product Code: MXK
Dated: July 18, 2003
Received: July 21, 2003

Dear Mr. Weatherby:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030719

Device Name: Pentacam Scheimpflug Camera

Indications For Use:

The Pentacam is designed to take photos of the anterior segment of the eye which includes the cornea, pupil, anterior chamber and lens of the eye. To evaluate:

- corneal shape,
- analyse condition of the lens (opaque crystalline lens),
- analyse the anterior chamber angle,
- analyse anterior chamber depth,
- analyse the volume of the anterior chamber,
- analyse anterior or posterior cortical opacity,
- analyse the location of cataracts (nuclear, subcapsular and or cortical), using cross slit imaging with densitometry,
- corneal thickness.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K030719

(Optional Format 3-10-98)